NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AVENTIS PHARMACEUTICALS INC., MARRELL PHARMACEUTICALS INC., and CARDERM CAPITAL L.P., Plaintiffs, v. IMPAX LABORATORIES, INC., *et al.*, Defendants.	Civil Action Nos. 02-1322 (GEB) 03-1179 (GEB) 03-1180 (GEB) 03-5108 (GEB) 03-5829 (GEB) 04-1075 (GEB) 04-1076 (GEB) 04-1077 (GEB) 04-1078 (GEB) 04-2305 (GEB) 04-3194 (GEB) 05-4255 (GEB) 06-5463 (GEB) 07-5054 (GEB) 07-5180 (GEB) 09-0325 (GEB) 09-4638 (GEB) 09-5179 (GEB) 10-1471 (GEB) **MARKMAN OPINION**

BROWN, Chief Judge

This matter comes before the Court on the parties' request for claim construction in a *Markman* hearing. The parties submitted their opening *Markman* briefs on September 2, 2010, and their responsive briefs on October 14, 2010. (Doc. Nos. 214, 215, 216, 219, 260, 262, 265, 267.)[1] The Court held a *Markman* hearing on November 10, 2010.

I. Background

This is a consolidated patent infringement case involving the pharmaceutical fexofenadine. Before the Court is the parties' request for claim construction in a *Markman* hearing. There are nine (9) patents at issue and twenty-nine (29) different disputed claim terms.

[1] All docket citations are to the 09-4638 case because several of the other dockets do not contain every document that the parties submitted.

Three of the patents are the "Method Patents" – United States Patent Numbers 6,037,353 (the "'353 patent"), 6,187,791 (the "'791 patent"), and 6,399,632 (the "'632 patent"). These patents share an identical specification and their claims are directed to administering fexofenadine to slightly different populations of people. Four of the patents are directed to fexofenadine formulations; these are United States Patent Numbers 6,039,974 (the "'974 patent"), 5,855,912 (the "'912 patent"), 6,113,942 (the "'942 patent"), and 5,738,872 (the "'872 patent"). The '942 and '912 patents share a written description. Finally, two of the patents are directed towards the process of making piperidine derivatives; they are United States Patent Numbers 7,390,906 (the "'906 patent") and 5,750,703 (the "'703 patent"). These patents also share a substantially identical written description.

On November 10, 2010, this Court conducted a *Markman* hearing. At the hearing, the Court construed eleven (11) of the twenty-nine (29) terms for the reasons it set forth on the record. In addition to those eleven (11) terms, the parties agreed that three (3) terms from the '906 patents were no longer relevant to the asserted claims and conferred to arrive at a construction for the term "wet granulation" in the '872 patent. These rulings resolved all of the claim construction issues in the '353, '912, '942, and '872 patents. The Court reserved its ruling on the remaining fourteen (14) terms; these terms consist of all five (5) terms from the '791 and '632 patents, four (4) terms from the '974 patent, two (2) terms from the '703 patent, and three (3) terms from the '906 patent.

This opinion addresses only the five (5) outstanding terms in the '791 and '632 patents. These patents share a written description because they stem from the same patent application. The patents do not claim a method of administering fexofenadine to patients in need of antihistamines generally; that method had been claimed in a previous patent, United States Patent

Number 4,254,129. Instead, the '791 and '632 patents claim a method for the administration of fexofenadine to several populations who have adverse side effects from a prior antihistamine, terfenadine.

The five (5) terms that this Court must construe involve the specific type of patient to whom fexofenadine should be administered. They are: (1) "patient . . . . susceptible to possible cardiac events associated with the administration of terfenadine," from claim 1 of the '791 patent; (2) "patient susceptible to QT prolongation and/or ventricular tachycardia when using terfenadine," from claim 9 of the '791 patent; (3) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite, while avoiding the concomitant liability of cardiac arrhythmias associated with the administration of terfenadine," from claim 1 of the '632 patent; (4) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite," from claim 5 of the '632 patent; and (5) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite and who is subject to QT prolongation and/or ventricular tachycardia when using terfenadine," from claim 9 of the '632 patent. (Joint Claim Construction Chart ("JCC") at 4-14; Doc. No. 210-1.) The Court will address the terms implicated in the other patents in separate opinions.

II. Discussion

A. Standard of Review

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. Specifically, the focus of a court's analysis must begin and remain on the language of the claims, "for it is that language that the patentee chose to

use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources; including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. *Id.*

When determining the meaning of the terms, the court must primarily consider the intrinsic evidence, including the specification and prosecution history. The specification "is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1587 (Fed. Cir. 1996). However, it is improper to import limitations from the specification to the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320, 1323 (Fed. Cir. 2005); *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364-65 (Fed. Cir. 2003). Courts "should also consider the prosecution history of the asserted patents" because it "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *Telcordia Techs., Inc. v. Cisco Sys.*, 612 F.3d 1365, 1372 (Fed. Cir. 2010); *Phillips*, 415 F.3d at 1317. Courts should, however, grant the prosecution history less weight than the specification because they are negotiations and "often lack[] the clarity of the specification." *Phillips*, 415 F.3d at 1317.

In addition to the specification and prosecution history, a court may also consider extrinsic evidence to determine the meaning of a term when an analysis of the intrinsic evidence

alone does not resolve the ambiguities of a disputed claim term. *Vitronics Corp.*, 90 F.3d at 1582-83.

The presumption of ordinary meaning may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term unlike its ordinary and customary meaning. *Brookhill-Wilk I, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). The patentee's intent to define the term must be clear before the court will use it to redefine the term and impose limits on the ordinary meaning. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005).

When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics*, 90 F.3d at 1582. The person of ordinary skill in the art is deemed to have read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313.

B. Analysis

1. Patient . . . susceptible to possible cardiac events associated with the administration of terfenadine

The parties suggest substantially different interpretations of this term. Plaintiffs propose a lengthy definition of this term that incorporates the '791 patent's definition of "patient" and several portions of the specification that suggest situations in which a patient would be susceptible to cardiac events. (JCC at 4; Doc. No. 210-1.) Defendants propose that the term means, "a hepatically impaired patient as defined at Co. 2, lines 53-59, making the patient susceptible to cardiac events associated with increased blood levels of terfenadine." (*Id.*) The primary difference between these two constructions is that Defendants' construction requires

the patient to be "hepatically impaired" whereas Plaintiffs' definition requires them only to be "a warm blooded animal" in line with the specification's explicit definition of "patient."

The Court adopts a construction similar to Defendants' construction, because while the language of the claims is open to a broader interpretation, the specification and the prosecution history limit the claimed patient population to those who are "hepatically impaired." Thus, the Court finds that the term, and the other similar terms at issue in this opinion, each refer to a subset of hepatically impaired patients.

While the claims define the invention, the intrinsic evidence's description of the invention as a whole can inform a court that a term's construction should be narrower than the meaning of the term in isolation. *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006); *see also Telecordia Tech., Inc., v. Cisco Sys., Inc.*, 612 F.3d 1365, 1374 (Fed. Cir. 2010). The specification may narrow this meaning because the "claims must be read in light of the specification" and because the specification is "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. If the patentee uses the specification to broadcast to the public that the invention is limited to a construction that is more narrow than the normal meaning of the claims, "the public is entitled to take the patentee at his word." *Honeywell*, 452 F.3d at 1318. Thus, where the specification makes statements about the entirety of the invention, and not just the embodiments of the invention, those statements can limit the scope of the claims.

For example, in *Honeywell*, the patentee described "this invention" or "the present invention" as a fuel filter on four occasions in the specification. 452 F.3d at 1318. Specifically, the specification used several phrases like "This invention relates to a fuel filter." *Id.* The Federal Circuit found that this statement limited the invention to fuel filters despite the fact that the claim language could be interpreted more broadly. *Id.* at 1318-19. In doing so, the Federal

Circuit was not swayed by the fact that the prosecution history contained a passage that suggested a broader interpretation by the patentee. *Id.*

This case is similar because the patentee repeatedly stated that the invention was limited administration of fexofenadine to hepatically impaired patients in the specification and in the prosecution history. Indeed, the specification repeatedly refers to treatment of "hepatically impaired patients" as "the present invention" and not merely as an embodiment. This is consistent with the title of the patent, which states the patent is a "method of providing an antihistaminic effect in a hepatically impaired patient." ('791 patent, Title.)

The specification repeatedly references the fact that "the present invention" is only a treatment of "hepatically impaired patients." As in *Honeywell*, these statements describe the entire invention, and not embodiments; thus, they may limit the scope of claims that otherwise could be interpreted more broadly. 452 F.3d at 1318. The Detailed Description of the Invention states that:

> The *present invention* relates to a method of providing an antihistaminic effect in a *hepatically impaired patient* in need thereof comprising administering said patient an effective antihistaminic amount of a compound of Formula (1).

('791 patent, 2:37-41) (emphasis added.) The Summary of Invention provides an identical statement that limits the invention to hepatically impaired patients:

> The *present invention* relates to a method of providing an antihistaminic effect in a hepatically impaired patient in need thereof comprising administering to said patient an effective antihistaminic amount of a compound of Formula (1).

('791 patent, 1:63-66) (emphasis added.) The Abstract also makes a similar statement: "The *present invention* relates to a method of providing an antihistaminic effect in a *hepatically impaired patient*[.]" ('791 patent, Abstract.) While these statements limit what the invention "relates to," rather than what the invention "is," the "relates to" language is the same language

that led the *Honeywell* court to determine that the specification limited the claims. 452 F.3d at 1318-19.

This limitation is consistent with the portions of the specification that center both the problem in the art solved by the invention and the remainder of the Detailed Description on hepatically impaired patients. When discussing the problem identified in the art – that terfenadine is not metabolized into terfenadine acid metabolite (an early name for fexofenadine) – the specification again points to hepatically impaired patients:

> Preliminary information indicates that in cases of *hepatic impairment*, significant concentrations of unchanged terfenadine can be detected with *the rate of acid metabolite formation being decreased*. In subjects with *normal hepatic function*, unchanged terfenadine plasma concentrations *have not been detected*.
>
> . . . .
>
> Surprisingly, it appears that *patients with impaired hepatic function* who are receiving terfenadine acid metabolite in sufficient amount so as to provide an antihistaminic effect will not experience cardiac events of QT prolongation and/or ventricular tachycardia.

('791 patent, 1:39-57) (emphasis added.) This passage also suggests that difficulties metabolizing terfenadine were *not detected* in non-hepatically impaired patients.

The remainder of the specification also reflects a focus on hepatically impaired patients. It defines a "hepatically impaired patient," mentions the advantages of the invention in "hepatically impaired patients" and suggests that, in order to practice the invention, the person of ordinary skill in the art is able to identify patients who are hepatically impaired. ('791 patent, 2:53-64, 3:10-14.) It does not contain passages that suggest how to identify other categories of patients.

At first blush, one portion of the specification does seem to support Plaintiffs' assertion that the patient population described in the claims is broader than those with hepatic impairment.

However, that portion appears prior to the portion of the specification that describes the present invention. Further, both the context of the passage and the prosecution history strongly suggest that this passage lists patients with hepatic impairment and then other examples patients who are hepatically impaired, and not patients with hepatic impairment and then other groups.

This portion of the specification, which the Court refers to as the "recently found" passage, states that:

> Recently, it has been found that patients with impaired hepatic function (alcohol cirrhosis, hepatitis), or on ketokonazole or troleandomycin therapy, or having conditions leading to QT prolongation (e.g., hypokalemia, congenital QT syndrome), may experience cardiac events of QT prolongation and/or ventricular tachycardia at the recommended dose of terfenadine.

('791 patent, 1:39-57.) This passage tacitly suggests that both people receiving "ketokonazole or troleandomycin therapy" and those "having conditions leading to QT prolongation" are separate from those with hepatic impairment because the passage lists them separately. However, as discussed below, the specification accounts for both of these groups and refocuses them as subgroups of patients who are hepatically impaired. The prosecution history also shows that the patentee understood that these groups were those with hepatic impairment. *See Telecordia Techs., Inc.*, 612 F.3d at 1372 (prosecution history is useful because it may show how the patentee understood the term).

First, this portion of the specification does not describe the invention – it is contained only in the portion describing the background of the field. ('791 patent, 1:39-57.) Thus, it is not directly relevant to what the invention constitutes. Second, the specification explains that patients on "on ketokonazole or troleandomycin therapy" are also hepatically impaired patients because the patentee's own definition of a "hepatically impaired patient" expressly includes them in its definition:

> A hepatically impaired patient is a patient having impaired liver function due to disease . . . or due to administration of a drug, such as *ketokonazole*, erythromycin *or troleandomycin*, which inhibits normal liver metabolic function.

('791 patent, 2:53-57) (emphasis added.) Thus, patients on ketokonazole and troleandomycin *are* hepatically impaired patients, despite being listed separately. This alone suggests that the items listed after patients with impaired hepatic function are merely subgroups of people that have impaired hepatic function. In addition, the sentence immediately after the "recently found" passage also accounts for those having conditions leading to QT prolongation by focusing that group of people back on those with hepatic impairment:

> Surprisingly, it appears that patients with *impaired hepatic function* who are receiving terfenadine acid metabolite [the drug whose administration constitutes the invention] in sufficient amount so as to provide an antihistaminic effect *will not experience* cardiac events of QT prolongation and/or ventricular tachycardia.

('791 patent, 1:53-57) (emphasis added.) The Detailed Description also contains a passage that focuses QT prolongation and/or ventricular tachycardia back on hepatically impaired patients; that passage states:

> When administered terfenadine at the recommended dosage, a hepatically impaired patient will experience increased levels of terfenadine in the blood and decreased levels of the acid metabolite over that expected with the non-hepatically impaired patient. Increased blood levels of terfenadine in turn may cause decreases in the action potential and in various membrane currents of cardiac cells which may trigger cardiac events of QT prolongation and/or ventricular tachycardia.

('791 patent, 2:60-3:1.) This focuses patients who have conditions leading to QT prolongation back on hepatically impaired patients.[2] Thus, all of the groups of patients listed in the "recently found" passage are hectically impaired.

[2] Certainly just because hepatically impaired patients would experience QT prolongation on terfenadine but not terfenadine acid metabolite, does not mean that all patients "having conditions leading to QT prolongation" are hepatically impaired patients. Logically, other patients with unrelated conditions could also experience QT

Further, the prosecution history makes plain that the patentee regarded the "recently found" passage as covering only hepatically impaired patients. *See Telecordia Techs., Inc.*, 612 F.3d at 1372 (prosecution history is useful because it may show how the patentee understood the term). The patentee repeatedly conceded or asserted in the prosecution history that this invention was limited to hepatically impaired patients and the patentee equated the patients listed in the passage with hepatically impaired patients. During prosecution, the Examiner rejected the claims because the prior art already taught a person of skill in the art to use fexofenadine as an antihistamine in patients. The examiner concluded:

> The only essential difference between the prior art and what is claimed herein is that *the patient is hepatically impaired*. One skilled in the art would be motivated to employ the compounds to treat *a hepatically impaired patient* since the indication since the indication in the prior art that the compound has antihistaminic activity renders the compound obvious for treating all patients in need of antihistaminic treatment[.]

(Supp. Karta Decl. Ex. 12, p.3; Doc. No.266-2.)

The patentee did not disagree with the examiner's characterization of the limitations of the patent. Indeed, when the patentee responded, he equated those patients "on ketokonazole or troleandomycin therapy, or having conditions leading to QT prolongation," the very patients Plaintiffs contend are not hepatically impaired, with "hepatically impaired patients." Specifically, the patentee stated

> Applicants respectfully assert that it is known that "patients with impaired hepatic function (alcohol cirrhosis, hepatitis), or on ketokonazole or troleandomycin therapy, or having conditions leading to QT prolongation (e.g., hypokalemia, congenital QT syndrome), may experience cardiac events of QT prolongation and/or ventricular tachycardia at the recommended dose of terfenadine" (page 2, lines 6-12 of the specification). *Thus, terfenadine*

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prolongation on terfenadine. However, given the immediate refocusing of this group on hepatically impaired patients and the specification and prosecution history's repeated statements that limit the scope of the invention to patients who are hepatically impaired, the Court is convinced that patients "having conditions leading to QT prolongation" are a subgroup of hepatically impaired patients, i.e. those having such conditions are also hepatically impaired.

> *treatment was associated with certain cardiac events in patients with hepatic impairment.*

(Supp. Karta Decl. Ex. 13, p.2; Doc. No. 266-2) (emphasis added.) In this passage, the patentee specifically uses hepatic impairment to summarize the other patients in the "recently found" passage. Thus, the patentee regarded the "recently found" passage that Plaintiffs assert refers to patients who are not hepatically impaired as listing patients with hepatic impairment and several other conditions that are subgroups of patients with hepatic impairment.

Further, the patentee described the invention as a treatment of hepatically impaired patients in the prosecution history. In response to the office action above, the patentee concluded:

> Applicants respectfully assert that the unexpectedly superior properties of the compounds of the present invention in the treatment of *hepatically-impaired patients* without the cardiac adverse events associated with terfenadine treatment, would not have been predictable with any reasonable expectation of success based on the teachings of the prior art. Therefore, the rejection of Claims 1-7 under 35 U.S.C. § 103 is improper.

(*Id.* at p.3) (emphasis added.)

In the subsequent interference action, the patentee also made clear that he regarded his invention as limited to patients that are hepatically impaired. Specifically, the patentee argued that the claims were "limited by their own language to patients who are at risk of possible cardiac events associated with the administration of terfenadine – i.e., *only patients who are hepatically impaired*" and that the patent did "not claim treatment of patients who are not at risk of adverse cardiac consequences from administration of terfenadine (i.e., *who are not hepatically impaired*.)" (Gannon Resp. Cert. at Ex.1, p.3; Doc. No. 267-1.) Finally, the patentee stated that "it is only patients *with impaired liver function* [i.e. those who are hepatically impaired] who

face an increased risk of cardiac arrhythmia from terfenadine[.]" (*Id.*)[3] Thus, this not only shows that the patentee understood his invention to be limited to hepatically impaired patients, but also that he argued this position in order to avoid a rejection before the Board of Patent Appeals and Interferences (the "Board").

Although, the Board ultimately rejected this construction and adopted a broader construction, it did so based upon a standard of review that is different from the one before this court.[4] Because the Board must anticipate what any court might construe the claims to cover, its role is to "accord the claims of an application and the counts of an interference 'the broadest meaning which they will reasonably support[.]'" (Gannon Resp. Cert. at Ex. 1, p.3; Doc. No. 267-1 (citing *Bocciarelli v. Huffman*, 109 USPQ 385, 388 (CCPA 1956).) This Court is the ultimate arbiter of the claims, and as a result, while it gives the patentee's words the full breadth of their plain meaning, it does so in light of the specification and prosecution history. These suggest that the person of ordinary skill would understand that the invention was limited to hepatically impaired patients. Thus, the rejection of the patentee's argument is not as relevant as the argument itself. It shows that the patentee, consistent with the specification and the remainder of the prosecution history, understood the patent and the specification's disclosure to be limited to hepatically impaired patients.

Because the specification contains numerous statements that limit the scope of the invention to only hepatically impaired patients and the prosecution history reveals that this is how the patentee regarded his invention, the Court finds that a person of ordinary skill in the art

[3] This also explains why patients with congenital QT syndrome must also be hepatically impaired in order to be within the subject invention – even those with congenital QT syndrome, an inborn heart condition, are not subject to the cardiac side effects unless they are also hepatically impaired.

[4] Further, the Board rejected the claims because it found that this construction found no support in the specification. While the subsequent examiner ultimately granted the claims as supported, it is not clear why. It is possible that the examiner used another, narrower construction or did so for a variety of other reasons. Thus, like in *Honeywell*, this portion of the prosecution history is not sufficiently persuasive to overcome the implications of the specification, the patentee's understanding of the invention, or the rest of the prosecution history.

would find that the claims are limited to a hepatically impaired patient. *See Phillips*, 415 F.3d at 1317; *Honeywell*, 452 F.3d at 1317-18. The particular scope of each claim in the '791 and '632 patents is directed to a subgroup of hepatically impaired patients.

This interpretation does not interpret the term "patient" to be different than the definition that the patent specifically set forth in the specification; rather, it interprets the way in which the additional words "patient . . . *susceptible to possible cardiac events associated with the administration of terfenadine*" modify the meaning of the word "patient." They require the patient to be hepatically impaired.

Thus, the Court construes the term to be limited to hepatically impaired patients and construes "patient . . . susceptible to possible cardiac events associated with the administration of terfenadine" to mean "a hepatically impaired patient as defined at Col.2, lines 53-59, who is also susceptible to possible cardiac events associated with the administration of terfenadine."

2. Remaining Terms

The remaining terms involve similar issues and can be easily resolved. These terms are:

(2) "patient susceptible to QT prolongation and or ventricular tachycardia when using terfenadine"— claim 9 of the '791 patent;

(3) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite, while avoiding the concomitant liability of cardiac arrhythmias associated with the administration of terfenadine" – claim 1 of the '632 patent;

(4) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite" – claim 5 of the '632 patent; and

(5) "patient in whom terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite and who is subject to QT prolongation and/or ventricular tachycardia when using terfenadine" – claim 9 of the '632 patent.

The Court first notes that the '632 patent is a continuation of the '791 patent, which in turn is a continuation of the '353 patent. (*See* '632 patent, Related U.S. Application Data.)

Thus, they share an identical specification and have large overlaps in their prosecution history. Consequently, the above discussion applies equally to both patents, because the specification that limits the claims and prosecution history that shows the specification's statements are limited to hepatically impaired patients are identical.[5]

Further, the primary dispute between the parties about these terms is identical to that discussed at length in the above term – whether the term refers only to hepatically impaired patients. (*See* Pls.' Br. at 20; Doc. No. 215; Pls.' Resp. Br. at 15, 21; Doc. No. 267.) Thus, the prior discussion decides the identical issue of whether the patients must be hepatically impaired and the Court will construe those terms in a similar manner. For example, the Court construes "patient susceptible to QT prolongation and or ventricular tachycardia when using terfenadine" to mean "a hepatically impaired patient as defined at Col.2, lines 53-59, who is also susceptible to QT prolongation and or ventricular tachycardia when using terfenadine."

Plaintiffs' additional argument that claim differentiation requires adopting its construction is unavailing. (*See* Pls.' Resp. Br. at 23-25; Doc. No. 267.) They argue that because the '353 patent claims the administration of fexofenadine to hepatically impaired patients, the Defendants' constructions are improper because their constructions cause the patents to overlap with the '353 patent. However, as demonstrated, each of these terms claims a different *subset* of hepatically impaired patients. Thus, this construction makes the scope of these claims similar but does not make it indistinguishable. This similarity is justified because the patentee admitted that the patents were obvious variants of one another when it agreed to a

[5] This Court does not rely on prosecution history estoppel for the *claim terms* of the '632 patent; rather it relies on the clear import of the specification, which is identical for both of the patents, and the prosecution history's description of that specification. However, it notes that the terms in the '632 patent are closely in line with the definition of the hepatically impaired patient in the patent. (*See* '632 patent, 2:53-59 ("In the hepatically impaired patient, terfenadine is not metabolized at the normal rate to the terfenadine acid metabolite.").) Further, the specification specifically states that problems with conversion of terfenadine to terfenadine acid metabolite had not been detected in patients who were not hepatically impaired. ('632 patent, 1:40-46.)

terminal disclaimer. (*See* '632 patent, Notice.) Further, claim differentiation is "a rule of thumb that does not trump the clear import of the specification." *Edwards Lifesciences, LLC v. Cook Inc.*, 582 F.3d 1322, 1332 (Fed. Cir. 2009). Here, the clear import of the specification and the prosecution history require the Court's construction.

Thus, the Court determines that each of these claim terms refer to subsets of patients with hepatic impairment. The Court construes those claims accordingly.

III. Conclusion

For the foregoing reasons the Court construes the terms in the '791 patent and the '632 patent to be limited to hepatically impaired patients as set forth in the accompanying order.

Dated: January 13, 2011

/s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.